

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board

Paper No. 40

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte BERNARD Malfroy-Camine

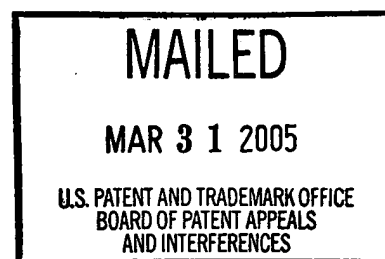
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Appeal No. 2005-0459  
Application No. 08/973,576

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ON BRIEF

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ELLIS, GRIMES, and GREEN, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-22 and 24, all the claims remaining in the application. Claim 23 has been canceled.

As a preliminary matter, we note the examiner's statement that claims 6 and 11 would be allowable if re-written in independent form. Office Action, mailed March 21, 2002, p. 5. In this regard, the appellant has stated that claims 6 and 11 stand separately. Brief, p. 3. We point out that claims 6 and 11 are not subject to any

rejection and, therefore, are not before us. Claim 1 is illustrative of the subject matter on appeal and reads as follows:

1. A method for making a lipidized protein, comprising the steps of:

attaching a lipid substituent having a hydrocarbon tail of at least 12 carbons to the protein by a covalent linkage of at least one lipoamine residue to a carbohydrate side chain to produce a lipidized protein; and

recovering the lipidized protein;

wherein:

the lipidized protein is capable of transvascular transport, enhanced organ uptake and intracellular localization.

The reference relied upon by the examiner is:

Horan et al. (Horan)

5,665,328

Sep. 9, 1997

The claims stand rejected as follows:

I. Claims 14-23 are provisionally rejected under the judicially-created doctrine of obvious-type double patenting as being unpatentable over claims 1, 2, 4-12, 24 and 29-33 of co-pending Application No. 08/483,944.

II. Claims 1-5, 7-10, 12-22 and 24 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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We have carefully reviewed the respective positions of both the appellants and examiner and find ourselves in substantial agreement with that of the appellant with respect to the enablement rejection. The appellant does not contest the double patenting rejection. Accordingly, we reverse Rejection II, and affirm Rejection I.

### Background and Discussion

The present invention is said to provide

methods for targeting a protein, such as an antibody, to intracellular compartments in a eukaryotic cell, methods for enhancing organ uptake of proteins, pharmaceutical compositions or modified proteins for use in human therapy, and methods for manufacturing modified proteins. [Specification, p. 1, para. 1].

As indicated by claim 1, above, the modified proteins of the invention comprise an attached lipid portion, wherein one or more acyl groups are linked to the protein through a carbohydrate side-chain and a covalent linkage.

The examiner argues that the appellants stated during interviews on February 17 and 22, 2000, that the Horan patent demonstrates that "it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. The prior art rejection has been dropped based on this interpretation of the Horan et al. reference." Answer, p. 4. According to the examiner, the claims encompass lipidized proteins containing a lipid having a hydrocarbon tail of greater than 12 carbons; therefore, the claims are broader than the enabling disclosure. Id.

We point out that it is the examiner's burden to establish that it would have required undue experimentation to make and use the claimed invention. In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). In considering the issue of undue experimentation, the court in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), set forth several factors which the examiner should bear in mind, and apply, when making an enablement rejection. Those factors include:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Here, we find that the examiner makes no mention of these factors, nor has he provided any explanation as to why it would require undue experimentation for one skilled in the art to make and use the invention. Rather, we find the examiner's only basis for arguing that the specification does not provide an enabling disclosure of the claimed invention is a statement which the appellants allegedly said during two previous interviews. We do not sustain rejections based on allegation.

Since we agree with the appellants that (i) the specification discloses how to obtain the materials necessary to make and use the invention; i.e., how to obtain proteins and lipids such as lipoamines, lipopolyamines and fatty acids; (ii) the

specification provides methods of attaching a lipid to a protein via a covalent linkage to a carbohydrate side chain of the protein; (iii) the specification discloses methods of testing or screening whether a lipidized protein localizes intracellularly or at the cell membrane; and (iv) the Horan patent describes binding a bio-affecting compound to the surface of procaryotic and eucaryotic cells and viruses using a hydrocarbon tail of suitable length, and is not directed to lipidized proteins which are capable of transvascular transport, enhanced organ uptake and intracellular localization as required by the claimed invention, we shall reverse the enablement rejection.

The provisional obvious-type double patenting rejection, however, stands on a different footing. Here, the appellants have agreed to file a terminal disclaimer and/or cancel the conflicting claims (Brief, p. 8). Accordingly, since the appellants do not contest the rejection, we affirm.

In view of the foregoing, the decision of the examiner is affirmed-in-part.

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No time period for taking any subsequent action in connection with this appeal  
may be extended under 37 C.F.R. § 1.136(a). See, 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART



JOAN ELLIS  
Administrative Patent Judge



ERIC GRIMES  
Administrative Patent Judge



LORA M. GREEN  
Administrative Patent Judge

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